

§ 870.3800 Annuloplasty ring.

(a) *Identification.* An annuloplasty ring is a rigid or flexible ring implanted around the mitral or tricuspid heart valve for reconstructive treatment of valvular insufficiency.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987]

§ 870.3850 Carotid sinus nerve stimulator.

(a) *Identification.* A carotid sinus nerve stimulator is an implantable device used to decrease arterial pressure by stimulating Hering's nerve at the carotid sinus.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any carotid sinus nerve stimulator that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a carotid sinus nerve stimulator that was in commercial distribution before May 28, 1976. Any other carotid sinus nerve stimulator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987; 61 FR 50706, Sept. 27, 1996]

§ 870.3925 Replacement heart valve.

(a) *Identification.* A replacement heart valve is a device intended to perform the function of any of the heart's natural valves. This device includes valves constructed of prosthetic materials, biologic valves (e.g., porcine valves), or valves constructed of a combination of prosthetic and biologic materials.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 9, 1987 for any replacement heart valve that was in commercial distribution before May 28, 1976, or that has on or before December 9, 1987 been found to be substantially equivalent to a replacement heart valve that was in commercial distribution before May 28, 1976. Any other replacement heart valve shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 52 FR 18163, May 13, 1987; 52 FR 23137, June 17, 1987]

§ 870.3935 Prosthetic heart valve holder.

(a) *Identification.* A prosthetic heart valve holder is a device used to hold a replacement heart valve while it is being sutured into place.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996]

§ 870.3945 Prosthetic heart valve sizer.

(a) *Identification.* A prosthetic heart valve sizer is a device used to measure the size of the natural valve opening to determine the size of the appropriate replacement heart valve.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996]

Subpart E—Cardiovascular Surgical Devices

§ 870.4075 Endomyocardial biopsy device.

(a) *Identification.* An endomyocardial biopsy device is a device used in a catheterization procedure to remove samples of tissue from the inner wall of the heart.

§ 870.4200

(b) *Classification.* Class II (performance standards).

§ 870.4200 Cardiopulmonary bypass accessory equipment.

(a) *Identification.* Cardiopulmonary bypass accessory equipment are devices that have no contact with blood and that are used in the cardiopulmonary bypass circuit to support, adjoin, or connect components, or to aid in the setup of the extracorporeal line, e.g., an oxygenator mounting bracket or system-priming equipment.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 54 FR 25049, June 12, 1989]

§ 870.4205 Cardiopulmonary bypass bubble detector.

(a) *Identification.* A cardiopulmonary bypass bubble detector is a device used to detect bubbles in the arterial return line of the cardiopulmonary bypass circuit.

(b) *Classification.* Class II (performance standards).

§ 870.4210 Cardiopulmonary bypass vascular catheter, cannula, or tubing.

(a) *Identification.* A cardiopulmonary bypass vascular catheter, cannula, or tubing is a device used in cardiopulmonary surgery to cannulate the vessels, perfuse the coronary arteries, and to interconnect the catheters and cannulas with an oxygenator. The device includes accessory bypass equipment.

(b) *Classification.* Class II (performance standards).

§ 870.4220 Cardiopulmonary bypass heart-lung machine console.

(a) *Identification.* A cardiopulmonary bypass heart-lung machine console is a device that consists of a control panel and the electrical power and control circuitry for a heart-lung machine. The console is designed to interface with the basic units used in a gas exchange system, including the pumps, oxygenator, and heat exchanger.

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(b) *Classification.* Class II (performance standards).

§ 870.4230 Cardiopulmonary bypass defoamer.

(a) *Identification.* A cardiopulmonary bypass defoamer is a device used in conjunction with an oxygenator during cardiopulmonary bypass surgery to remove gas bubbles from the blood.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987]

§ 870.4240 Cardiopulmonary bypass heat exchanger.

(a) *Identification.* A cardiopulmonary bypass heat exchanger is a device, consisting of a heat exchange system used in extracorporeal circulation to warm or cool the blood or perfusion fluid flowing through the device.

(b) *Classification.* Class II (performance standards).

§ 870.4250 Cardiopulmonary bypass temperature controller.

(a) *Identification.* A cardiopulmonary bypass temperature controller is a device used to control the temperature of the fluid entering and leaving a heat exchanger.

(b) *Classification.* Class II (performance standards).

§ 870.4260 Cardiopulmonary bypass arterial line blood filter.

(a) *Identification.* A cardiopulmonary bypass arterial line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (blood clots or pieces of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. It is used in the arterial return line.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has